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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE 09/241,497 HAMEL 02/01/99 M 4666 **EXAMINER** IM52/1023 SAMUELS GAUTHIER & STEVENS SINES, B ARLENE J POWERS **ART UNIT** PAPER NUMBER 225 FRANKLIN STREET SUITE 3300 1743 BOSTON MA 02110 DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

	Application No.	Applicant(s)
Office Action Summary	09/241,497	HAMEL ET AL.
	Examiner	Art Unit
	Brian J. Sines	1743
The MAILING DATE of this communication appears on the cover sheet with the correspondence address		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status		
1) Responsive to communication(s) filed on 7/10	<u>/2001</u> .	
2a)☐ This action is FINAL . 2b)⊠ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4) Claim(s) 1-7 is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1,2 and 5-7</u> is/are rejected.		
7)⊠ Claim(s) <u>3 and 4</u> is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)☐ The specification is objected to by the Examiner.		
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12) The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.		
Attachment(s)	A) [] Intoi 0	nu (PTO 413) Panar Na(a)
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	5) 🔲 Notice of Informal	ry (PTO-413) Paper No(s) Patent Application (PTO-152)
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Art Unit: 1743

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Taggart (US 5,882,603). Taggart discloses a disposable pipette tip rack or magazine. As shown in Figure 1, Taggart discloses a pipette tip rack or magazine comprising a rectangular plate or tip holder (10) with a flat upper surface, having an edge, which encloses an inner region containing an array of through-openings (11) for vertically receiving and retaining pipette tips (P). The plate (10) has a flat upper surface. The tip holder (10) is not free standing and therefore requires the support (14) for use. holder (10) is inserted into and rests within the support (14). The edge of the tip holder (10) rests on the support planes (24a,b) or ledges of the support (14). The support additionally comprises a varying number of support members (32) which can provide additional support to the tip holder (10). Taggart recognizes that the support members (32) must have sufficient strength so that the tip holder (10) does not substantially deflect down or warp when the pipette tips (P) are removed by an instrument which presses down onto the apparatus within the geometric center so as to wedge the pipette tips (P) securely onto the pipetting instrument (lines 58 – 65, column 3).

Art Unit: 1743

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rainin (US 4,577,760). Rainin et al. teach an apparatus for supporting pipette tips. As shown in figures 1 – 12, Rainin et al. teach a pipetting chamber (12) with a generally U-shaped ledge (90), a pipette tip magazine (22) adapted for insertion into and removal from an operative position in the chamber supported on the ledge (90). The magazine comprises a generally rectangular flat plate (22) having an edge (15) surrounding an inner region where the edge is configured to be supported on the ledge (90). The inner region has an array of through openings (118) for vertically receiving and retaining pipette tips (26, 28) (see Description of Preferred Embodiments section). The plate is manufactured from a polymeric resin (col. 4, lines 46 – 55).

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Stolp (US 56,309,980). Stolp teaches a pipette tip mounting and transfer apparatus. As shown in figures 1 – 4, Stolp teaches a pipetting chamber (56) with a generally U-shaped ledge, a pipette tip magazine (32) adapted for insertion into and removal from an operative position in the chamber supported on the ledge (90). The magazine comprises a generally rectangular flat plate (32) having an edge (52) surrounding an inner region (50) where the edge (52) is configured to be supported on the ledge (44). The inner region has an array of through openings (34) for vertically receiving and retaining pipette tips (12) (see Description of Preferred Embodiments section). The plate is manufactured from a polymeric resin (col. 8, lines 12 – 21).

Art Unit: 1743

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taggart as applied to claims 1 and 5 above, and in view of Stolp and Weast et al. (1984). Taggart discloses a disposable pipette tip rack or magazine containing the structural features of your device as similarly described in the language of claim 1. As shown in Figure 1, Taggart discloses a pipette tip rack or magazine comprising a rectangular plate or tip holder (10) with a flat upper surface, having an edge, which encloses an inner region containing an array of through-openings (11) for vertically receiving and retaining pipette tips (P). The plate (10) has a flat upper surface. The tip holder (10) is not free standing and therefore requires the support (14) for use. The tip holder (10) is inserted into and rests within the support (14). The edge

Art Unit: 1743

of the tip holder (10) rests on the support planes (24a,b) or ledges of the support (14). The support additionally comprises a varying number of support members (32) which can provide additional support to the tip holder (10). Taggart recognizes that the support members (32) must have sufficient strength so that the tip holder (10) does not deflect down or warp when the pipette tips (P) are removed by an instrument which presses down onto the apparatus within the geometric center so as to wedge the pipette tips (P) securely onto the instrument (lines 58 – 65, column 3). Although, Taggart teaches that a variety of suitable materials, such as various plastics, metals, ceramics and combinations of such materials, may be used in the construction of the support and tip holder, Taggart is deficient in identifying a specific plastic material (lines 39 -51, column 4). Stolp recognizes that tip holders should be of a material and have a shape that will prevent warping as pressure is applied (col. 6, lines 8 – 21). As taught by Stolp for example, pipette tip racks are commonly manufactured using polymeric thermoplastic resins, such as molded polypropylene or other related pressure-resistant durable plastics (lines 12 – 21, column 8). Furthermore, as taught by Weast et al., the mechanical properties characteristic of polycarbonate thermoplastics are indicative of greater mechanical strength and stiffness in comparison to unmodified and copolymer polypropylene thermoplastics (pp. C-780 – 782). For example, the modulus of elasticity of unfilled polycarbonate thermoplastics is $290 - 325 \times 10^3$ psi, whereas the modulus of elasticity for unmodified polypropylene thermoplastics is much lower at $1.4-1.7 \times 10^3$ psi. In addition, the tensile strength of unfilled polycarbonate thermoplastics is 8,000 -9,500 psi, whereas the tensile strengths of unmodified and copolymer polypropylene

Art Unit: 1743

thermoplastics are lower at 4,300 – 5,500 psi and 2,900 – 4,500 psi, respectively. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a thermoplastic polymer resin having greater mechanical strength properties, such as a polycarbonate resin, instead of a less mechanically robust polymeric resin, such as a polypropylene resin, in order to manufacture a pipette tip magazine having the desired mechanical strength, inherent stiffness and deflection properties as stated in the claims. The courts have decided that selection of a known material based on its suitability for the intended use is within the ambit of one of ordinary skill in the art [In re Leshin, 125 USPQ 416 (CCPA 1960)]. Stolp additionally teaches a disposable pipette tip rack which is stackable when filled with pipette tips and is a commonly found feature in the design of disposable pipette tip racks as shown in Figure 2. It would have been further obvious to one of ordinary skill in the art at the time the invention was made to manufacture a disposable pipette tip magazine which was stackable when filled with pipette tips.

Allowable Subject Matter

Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Taggart, Rainin, Stolp and Weast et al. do not teach or suggest the manufacture of a pipette tip magazine for use in an automated pipetting system from a

Art Unit: 1743

polycarbonate resin containing glass fiber and wherein the amount of glass fiber incorporated is approximately 20 to 40 % by weight of the polycarbonate.

Response to Arguments

Applicant's arguments filed 7/10/2001 have been fully considered but they are not persuasive.

In response to applicant's argument that the prior art structure cannot be utilized in an automated pipetting system, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

With regard to the anticipatory references, it is the applicant's burden to explain that a tip holder made according to either Stolp or Rainin does not inherently possess the required stiffness. The applicant states that the downward deflection of the plate resulting from the applied force is dependent upon both the stiffness of the material and the size dimensions of the plate. Therefore, claim 1 is incomplete since the properties and characteristics of the plate, in particular the material composition, which are deemed responsible for imparting the desired deflection characteristics, are not stated in the claim. Because of the lack of clarity in the claims regarding how the force is applied, the Taggart reference is deemed to anticipate the claimed property within the scope used by the examiner. Certainly, applying the force at a position adjacent to the

Art Unit: 1743

supported edge would produce little if any deflection at the geometric center of the tip holder. Relative to the obviousness combination, both Taggart and Stolp recognize that the tip holder should be prevented from warping, or that the warping should be minimized, when pressure is applied. The Stolp reference shows that this may be done by the shape and material of the tip holder. Thus, it would have been obvious to one of ordinary skill in the art to modify Taggart to reduce the need for supporting the tip holder by using either a shape or material or both that would have given this ability to the tip holder. In conjunction with this modification, Weast et al. show that one of ordinary skill in the art would have recognized that plastics, such as polycarbonate have inherent properties of strength or stiffness, which exceed those of a material such as polypropylene. With regards to the specification of the structure of the edge of the plate, as shown in figure 1A of Stolp, an edge or lower surface (52) is used to define the area around the outer perimeter of the magazine. Contrary to the applicant's assertion. the geometric center of the plate is not considered an inherent limitation. The edge region or lower surface (52) defines an inner region or upper surface (50) of a tip magazine (32). The geometric center may be considered a point location or a specified area within the inner region of the plate.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

BJS October 20, 2001

> Supervisory Patent Examiner Technology Center 1700

III Wards

Page 9